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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,063	12/10/2003	Jon Carl Marlowe	9301-232-999	9078
20583	7590	05/31/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SIMS, JASON M	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/734,063	Applicant(s) MARLOWE ET AL.	
	Examiner Jason M. Sims	Art Unit 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/29/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election with traverse of group II claims 14-22, in the reply filed on 2/24/2006 is acknowledged. The traversal is on the ground(s) that group I and group II are directed to a computer method for preparing a binding-ready biological sample. This is not found persuasive because the related inventions are distinct if the inventions as claimed are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). The inventions are mutually exclusive if they have different modes of operations or unique method steps, which have different results. For example, group I claims involve unique method steps such as determining whether pooling and splitting need to occur and if so, then generating a worklist containing these instructions. Additionally, the claims of group I determine specific calculations based on UV spectrophotometer data and use a LIMS to perform said calculations and include performing calculations of fluorescent dye incorporation. Claims of Group II involve acquiring a tissue sample and extracting a constituent sample from said tissue and including said tissue in the inventory. Additionally, claims of group II involve an operator for moderating the inventory. In the instant case, the different and distinct groups have different modes of operations, functions, and effects, which are deemed as mutually exclusive. Therefore, some common limitations are not persuasive as the invention as a whole is being evaluated for examination distinctness.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bluestein et al. (US P/N 4,780,423) in view of Lucas (US P/N 6,996,538).

The claimed invention is directed to a method for preparing a binding-ready biological sample to be used in a said binding assay and an automated inventory checking system. The method involves receiving a design for a binding assay, preparing an experiment design and choosing a robot method for generating said binding-ready biological sample, generating work instructions, and executing said work instructions on robot stations to generate the binding-ready biological sample. The method also involves an automation method for checking supplies and materials required for experiment design and ascertaining whether there are enough materials in inventory.

Bluestein et al. teaches the first step of claim 14 at col. 6, lines 35-48. Bluestein et al. discusses receiving an IMMOPHASE radioimmunoassay kit for performing an assay as required in the first step, which cites receiving a binding assay design.

Bluestein et al. teaches the second step of claim 14 at col. 8, lines 10-31. Bluestein et al. explicitly discusses changes made in the radioimmunoassay kit used in

Example 1 as preparative steps for designing an experiment for generating a binding-ready biological sample.

Bluestein et al. teaches the third step of claim 14 at col. 8, lines 61-69 and col. 9, lines 1-30. Bluestein et al. discusses the use of the Screen Machine System manufactured by Pandex Laboratories as the choice of a robot method for generating a binding ready biological sample and executing work instructions on robot stations to generate the binding ready biological sample. At col. 9, lines 8-12, Bluestein et al. discusses a microprocessor that can be programmed for generating work instructions for generating biological sample, such as adding wash solutions and reagents. At col. 9, lines 13-15, Bluestein et al. discusses the execution of work instructions for generating the biological sample using the SCREEN MACHINE.

Bluestein et al. teaches optimizing materials usage and plate layout for generating biological sample at Col. 8, lines 15-26 and lines 53-57, where changes were made for creating high precisional capabilities and a comparison shows that the assay of this invention is capable of achieving more rapid test results, which is a result of optimizing materials usage and plate layout.

Bluestein et al. teaches claims 20 and 22 at col. 4, lines 62-69 and col. 5, lines 1-4. Bluestein discusses the biological sample as being a receptor tissue protein. Bluestein also discusses the assay as comprising a ligand and a specific binding partner to the ligand, which is a type of hybridization assay.

Bluestein et al. teaches part of claim 20 at col. 4, lines 62-69 and col. 5, lines 1-4. Bluestein discusses the biological sample as being a receptor tissue protein. If the

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sample in the assay is a receptor tissue protein, then it necessitates an extraction in order to isolate the protein from the tissue for use in the assay. Bluestein does not teach updating inventory after extracting a constituent sample. Additionally, Bluestein et al. does not teach an automation method for checking supplies and ascertaining whether there are enough materials in inventory, sending a request, and notifying an operator if there are not enough materials in inventory.

Lucas teaches claim 16, checking inventory for required materials, at col. 2, Lines 45-53. Lucas discusses an inventory management system, which automatically checks supplies and materials required as needed.

Lucas teaches claim 17, at col. 8, lines 65-67 and col. 9, lines 1-10. Lucas discusses sending an inventory request, receiving a list of materials and ascertaining whether there are enough materials.

Lucas teaches claim 18, at col. 9, lines 63-67 and col. 10, lines 1-53. Lucas discusses sending an inventory request containing a list of materials as a customer selecting search criteria which queries a list of products and product descriptions that match the inventory request and returns the information.

Lucas teaches claim 19, at col. 10, lines 33-68 and col. 11, lines 1-46. Lucas discusses sending inventory requests when not enough materials may be available and notifying an operator or sales consultant and continue scanning orders until requests are fulfilled.

Lucas teaches part of claim 20 at col. 9, lines 50-55. Lucas discusses updating customer inventory.

Lucas does not teach a method for preparing a binding-ready biological sample for a binding assay.

It would be obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bluestein et al. with Lucas because the automating inventory checking system of Lucas will enhance the automation of the automation system of generating a binding assay.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)-272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 30 May 2016  
JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER